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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,785	12/20/2000	William J. Curatolo	PC10755AJTJ	8464

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PATENT DEPARTMENT
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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
08/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	09/742,785	CURATOLO ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,29,156 and 164-168* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,29,156 and 164-168* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appeal Brief filed on 2/22/2010, PROSECUTION IS HEREBY REOPENED. New rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618.

2. Claims 1, 2, 29, 156 and 164-168 are pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 29, 164, 165 and 167 and 168 are rejected under 35 U.S.C. 102(e) as being anticipated by Curatolo et al. (US 6,548,555 B1).

5. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

6. Curatolo describes compositions comprising physical mixture or granulated mixture of a crystalline or amorphous drug or salt of the drug and polymers (column 3, line 10 to column 6, line 67). The physical mixture and the crystalline form of the drug meet the limitations of claims 1, 164. The granules meet the limitation of particles of claims 1 and 164. The polymers are listed as hydroxypropylmethylcellulose acetate succinate (HPMCAS), cellulose acetate trimellitate (CAT), cellulose acetate phthalate (CAP), hydroxypropylcellulose acetate phthalate (HPCAP), hydroxypropylmethyl-cellulose acetate phthalate (HPMCAP), and methylcellulose acetate phthalate (MCAP) and mixtures (column 3, lines 40-50; column 4, lines 11-16) and these polymers, specifically the HPMCAS, CAP, CAT, HPCAP meet the polymer requirements of claims 1 and 164. Aqueous solubility of up to about 1 to 2 mg/mL as recited in claims 1 and 164 or less than 0.01 mg/mL as recited in claim 167 is a property of the drug and the

composition of Curatolo would also have those properties. The recitation that the composition achieves a maximum equilibrium concentration of at least 2-fold of a drug … in claims 1 and 164 is a property of the drug composition and property of a composition is not separable from the composition; and thus the composition of Curatolo would inherently achieve said equilibrium concentration relative to the drug. Some of the basic drugs names are sertraline and ziprasidone (column 7, line 3 and 4). While Curatolo defines the salt to mean pharmaceutically acceptable salt, example form uses the mesylate of the carboxamine drug listed as one of the drugs (column 6, lines 66,67), ziprasidone HCl is used in Example 3.1. For claims 1 and 164 and 165 the mesylate form of the carboxamide meets the non-HCL form of the drug requirement of these claims. Curatolo mixes the polymer and the drug in the absence of solvent (column 5, lines 1-7) and claim 168 is met. The Carboxamide drug is an antiviral drug so that claim 29 is met.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 29, 156, 164, 165, 167 and 168 are rejected under 35 U.S.C. 103(a) as being obvious over Curatolo et al. (US 6,548,555 B1) in view of Busch et al. (US 6,110,918).

10. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

11. Curatolo has been described above to anticipate claims 1, 2, 29, 164, 165 and 167 and 168. while Curatolo specifically names ziprasidone and the salt (see column 7, line 4; column 4, lines 66, 67), Curatolo uses ziprasidone HCl in example 3, Table 3.1) and not the non-HCl salt of ziprasidone; ziprasidone is antipsychotic agent. However ziprasidone is available as the mesylate salt and used as an antipsychotic drug (see the abstract of Busch). Therefore, taking the teachings of Curatolo and the teaching of Busch that ziprasidone can also be in the form of

the mesylate, one having ordinary skill in the art at the time the invention was made would reasonably expect that substituting the mesylate for the hydrochloride salt would also be expected to be successfully formulated with HPMCAS, CAP, CAT or HPCAP for effective treatment of psychosis. One having ordinary skill in the art would be motivated to do so because one salt form of a drug can be used in place of the other with the expectation of achieving the same delivery goal. Therefore, the ziprasidone salt as the mesylate meets the requirements of claims 1, 164 and 156.

12. Claims 1, 2, 29, 164 and 166-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 5,496,561).

13. Okada discloses a controlled release pharmaceutical composition comprising crystalline form of a drug (column 3, line 32); polymer such as hydroxypropylmethylcellulose acetate succinate, hydoxypropylmethylcellulose phthalate, cellulose acetate phthalate and carboxymethylethyl cellulose (column 3, lines 36-39, column 4, lines 20-25); plasticizers such as triethyl citrate, triacetin, polyethylene glycol, castor oil, polysorbitan monooleate, glycerin fatty acid ester (column 5, lines 5-8). Okada contemplates coating the drug core with such polymers such as HPMCAS and EUDARGIT amongst others (column 4, lines 11-44).

14. The instant application claims a composition that comprises a drug in a pharmaceutically acceptable solubility-improved form and a concentration-enhancing polymer is a salt and several examples of drugs that are suitable in the instant invention are listed in the specification (page 30, line 31 to page 31 line 5, page 35, line 13 to page 36 line 26 and page 26, line 30 to page 29 line 18). In the instant application, the recitation that the composition achieves a maximum equilibrium concentration of at least 2-fold of a drug … is a property of the drug composition

and property of a composition is not separable from the composition; and thus the composition of Okada would inherently achieve said equilibrium concentration relative to the drug.

15. Instant claims 2 and 167 recite the property of the composition and the teaching of Okada meets the limitations of said claims; diclofenac sodium, which is one of the drugs disclosed in Okada has analgesic, anti-inflammatory and antipyretic activities; and thus Okada meets the limitation of instant claim 29 and the non-HCL salts of drug in claims 1 and 164. Claim 168 is a product by process so that claim 168 is met by Okada. Aqueous solubility of up to about 1 to 2 mg/mL as recited in claims 1 and 164 or less than 0.01 mg/mL as recited in claim 167 is a property of the drug so that Okada meets these claims

16. The solubility of the drug as recited in claims 1 and 164 is the property of the drug and if a prior art teaches the same drugs that are of low solubility, then, the drug in the prior art would inherently have that solubility recited in claims 1 and 164.

17. Claim 167 also says that the aqueous solubility is less than 0.01 mg/mL at pH of 1 to 8. This solubility is also a property of the drug and because the prior art teaches the same drugs such as diclofenac, which is one of the drugs disclosed in Okada has analgesic, anti-inflammatory and antipyretic activities; and thus Okada meets the limitation of instant claim 29. Therefore, the drug of the prior art would also have this property.

18. While Okada contemplates the use of polymers including HPMCAS and EUDRAGIT, the example in Okada uses EUDRAGIT and not the cellulose enteric polymers of the claims. However, because both EUDRAGIT and HPMCAS are enteric polymers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use one HPMCAS enteric polymer in place of the EUDRAGIT used in the example and reasonably expect to obtain the same result.

Response to Arguments

19. Appellant's arguments filed 3/30/2010 have been fully considered but they are not persuasive.

20. Appellant argues that Okada while suggesting that the drug core is over coated with HPMCAS, HPMCP or CAP, does not teach how to achieve the coating; that there is no exemplification of a composition that contains HPMCAS and drug.

21. Response: The examiner acknowledges that Okada does not specifically teach how to coat the core. But, coating a core with a polymer is well known in the art and when for example, the core particles are mixed with polymer the polymer would coat the particles.

22. The examiner also agrees with the appellant that Okada does not display examples of compositions containing the drug and HPMCAS. However, Okada is clear that the core particles can be coated by the polymers listed above. Okada exemplifies EUDRAGIT with the sodium salt of diclofenac. But, one enteric polymer can be used in place of another enteric polymer with the expectation of achieving the same effect. While Okada did not exemplify HPMCAS with the drug, the prior art reference is not is not limited to the examples but the reference as a whole must considered.

23. No claim is allowed.

24. NB: A power of attorney may be necessary in this application since the attorney prosecuting this case now is different from the previous attorney and no power of attorney has been filed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0594.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618